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## DEPARTMENT OF ENERGY

Office of Environment, Safety and Health

10 CFR Part 602

Epidemiology and Other Health Studies Financial Assistance  
Program

AGENCY: Office of Environment, Safety and Health, Department of Energy.

ACTION: Final rule.

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**SUMMARY:** The Department of Energy (DOE) Office of Environment, Safety and Health (EH) is issuing a rule to implement an Epidemiology and Other Health Studies Financial Assistance Program. The rule will support EH use of financial assistance awards when they are the appropriate instruments for programmatic activities. The rule will also facilitate a fully open and competitive process for obtaining financial assistance awards. This action is taken to support EH's mission to protect the health of DOE workers, as well as other individuals associated with energy production, transmission, and use.

**EFFECTIVE DATE:** The final rule is effective March 2, 1995.

**FOR FURTHER INFORMATION CONTACT:** Dr. Heather Stockwell, Acting Director, Office of Epidemiology and Health Surveillance (EH-42), U.S. Department of Energy, Washington, DC 20585; facsimile: 301-903-4677; telephone: 301-903-3721.

**SUPPLEMENTARY INFORMATION:**

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## I. Introduction

DOE is amending chapter II of title 10 of the Code of Federal Regulations (CFR) by adding a new part 602 for use of financial assistance awards to support the EH program of epidemiology and other health-related research. EH health-related financial assistance awards previously were made under provisions of the generally applicable DOE Financial Assistance Rules (10 CFR part 600). Part 600 provides basic DOE procedures for the award and administration of financial instruments, but does not contain program-specific requirements for particular types of financial assistance awards. Part 602 builds on and supplements part 600 by describing the special needs and requirements of the EH Epidemiologic and Other Health Studies Financial Assistance Program. Because the rules work together, it is necessary to refer to both part 600 and this proposal to obtain a comprehensive picture of program procedures. The rule, in conjunction with part 600, provides a framework for an ongoing, comprehensive program for the receipt, review, and evaluation of award applications, and provides specific guidance for pre- and post-award administration. A discussion of the major provisions of the rule, organized by rule section, follows.

## II. Discussion of Comments on Proposed Rule

DOE issued a proposed rule in the Federal Register on October 18, 1993, [58 FR 53671] to amend existing regulation 10 CFR part 600 to support EH use of financial assistance awards when they are the appropriate instruments for programmatic activities. The proposed rule was to also facilitate a fully open and competitive process for obtaining financial assistance awards. Comments were requested through November 17, 1993. DOE received written comments from two university research administration offices.

One commentator stated that the proposed rules appear reasonable and expressed willingness to work productively with DOE. The other

commentator expressed concern about EH having a financial assistance rule separate from other DOE program offices. The correspondent noted that Federal agencies are now required to eliminate unnecessary internal management regulations and questioned the need for the proposed EH rule. The commentator urged DOE to withdraw the proposed rule and to administer the Epidemiology and Other Health Studies Financial Assistance Program under the existing Office of Energy Research Financial Assistance Rule (10 CFR part 605). Noting that the proposed rule is similar to 10 CFR part 605, the commentator suggested that EH issue annual program announcements under that existing rule.

DOE has decided not to withdraw the rule for three reasons. First, DOE needs program-specific financial assistance rules to address unique mission requirements. Section 602.5, for example, describes specific EH program areas. Focusing upon the health of the [[Page 5839]] DOE workforce and related issues, these program areas are distinct from those of other DOE offices. In light of the Secretary of Energy's emphasis on protecting worker and community health, DOE must have a targeted financial assistance mechanism to ensure these areas are properly supported. Further, section 602.9 commits DOE to use independent evaluators to ensure credible and inclusive peer review. This explicit commitment is essential, given the high degree of public and congressional interest in occupational and environmental health studies pertaining to DOE.

Second, DOE is currently reviewing its financial assistance rules under Executive Order 12861. Some of the revisions may eliminate the need for separate program rules by better accommodating the desire of assistance programs to address their unique mission in the use of financial assistance.

Third, the large majority of DOE financial assistance regulations are already in place at 10 CFR part 600. This means that nearly all the requirements for audits, patents, financial management, and many other administrative activities remain unaffected by the EH rule. The EH rule merely defines a narrow, but significant, range of programmatic needs. Codification of these needs will help those seeking financial assistance to understand EH mission requirements and to develop effective proposals to address these requirements.

### III. Final Rule

Section 602.1 defines the purpose and scope of part 602 as setting policies and procedures for award and administration of EH health related research, education/training, conferences, and communication activities through financial assistance awards.

Section 602.2 establishes applicability, stating that part 602 requirements apply to awards made on or after the effective date of the

rule. It also states that part 602 supplements and does not replace 10 CFR part 600.

Section 602.3 defines terms used in the rule. As definitions in 10 CFR part 600 apply to terms in part 602, it was unnecessary to provide definitions except for a few terms with special meaning for the EH program of epidemiologic and other health studies.

Section 602.4 governs deviations from the rule. It allows for single-case deviations from part 602 if authorized by the Assistant Secretary for EH, the Head of the Contracting Activity, or their designees. There is no provision for class deviation. If a proposed single-case deviation from part 602 is also a deviation from 10 CFR part 600, the provisions for deviations contained in both rules will apply. Section 602.4 allows for program control over single-case deviations of a purely program nature, but assures that deviations relating to generic provisions are also authorized pursuant to the procedures contained in the generic rules.

Section 602.5 establishes that research, education/training, conferences, and communication activities in various EH program areas are eligible for awards under part 602. The program areas are listed in the section and may be expanded by Federal Register notice.

Section 602.6 sets forth eligibility for awards. The only categorical restriction pertains to Federal agencies. DOE anticipates that most recipients will participate through institutions because of the substantial material and business management resources needed to conduct projects under the program.

Section 602.7 establishes procedures relating to award solicitation, including mechanisms to publicize award availability and distribute application forms and other information. The section also states that DOE reserves the right to fund, in whole or in part, any, all, or none of the applications submitted under award solicitations.

Section 602.8 sets forth provisions and procedures required to apply for an award, including prescribed forms and other information requirements. Nothing in this section or in 10 CFR part 600 will prohibit appropriate contacts between potential applicants and DOE staff prior to submission of applications. Such contacts may include discussions of broad advice on research areas of interest or administrative procedures. Requests for information that might provide an unfair competitive advantage are not permitted.

Section 602.9 describes procedures for application evaluation and selection. While DOE employees will evaluate the applications and make award selections, every effort will be made to use reviewers apart from DOE employees and contractors. Use of outside reviewers will ensure that the best experts are available to conduct technical evaluations and will also ensure open and credible peer review of applications. This is also in keeping with the Federal Government's tradition of

using a broad range of peer reviewers to evaluate the scientific and technical merit of research proposals.

Section 602.9(d) sets forth the evaluation criteria. They are necessarily broad because of the wide variety of projects and approaches anticipated. The criteria are consistent with those used by other DOE offices and Government agencies in similar programs. Section 602.9(d)(5) will permit DOE to establish, in a notice of availability or separate solicitation, evaluation criteria consistent with the purpose of part 602 other than those listed in the rule.

Section 602.9(g) states that selection of applications for award will be based upon findings of technical evaluations, including peer reviews. These evaluations will be conducted according to procedures specified in the EH Merit Review System, which was published as a Program Notice in the Federal Register on November 25, 1992.

Section 602.10 sets forth certain additional requirements that are not specifically addressed in 10 CFR part 600. The section requires recipients performing research involving human subjects, recombinant DNA molecules (and/or organisms and viruses containing recombinant DNA molecules) or warm-blooded animals to comply with certain Federal requirements. While these concerns are not common under DOE-funded projects, they require special attention because of their importance. The treatment of these matters is similar to that required by other Federal agencies.

Section 602.11 provides for a project period that is long and flexible enough to accommodate research. Measurable results often take years and cannot be accurately predicted. On the other hand, DOE must assure adequate programmatic review. Accordingly, initial project periods of up to 3 years will be the norm. Project periods may exceed 5 years only if DOE makes a renewal award or allows an extension. To assure adequate financial accountability and review, section 602.11(b) provides a general budget period of 12 months, which is the norm as provided under 10 CFR 600.106. To allow for those projects that are not suited to this limitation, DOE may allow for a budget period of 24 months.

Section 602.12 establishes that cost sharing, while always welcome, is not a factor in evaluating or selecting applications under the program. DOE wishes to fund the best projects, not just those of institutions capable of cost sharing arrangements.

Section 602.13 states that DOE is liable only for the funds noted in the Notice of Financial Assistance Award. No additional obligations are required to support or extend a specific award.

Section 602.14 allows fee payment to small business concerns under appropriate circumstances to permit all qualified parties to participate in the program. In establishing the need for and the amount of any such fee, the intrinsic benefits of an award provided to

the recipient, such as advance payments and title to property, will be taken into consideration.

Section 602.15 establishes that DOE will not provide indirect costs for conferences and scientific/technical meetings. Conferences and meetings do not require the institutional infrastructure needed to support research projects.

Section 602.16 sets forth requirements pertaining to national security classified information. DOE does not intend this program to use or develop classified information. If projects develop information that may be classified, the section provides requirements for its handling and review. Such projects may be terminated by mutual agreement.

Since the initial publication of this rule the designated title of this official has been changed from Director of Classification to Director of De-classification.

Section 602.17 describes requirements for project continuation funding and reporting. This section outlines the varieties of reports required for project accounting and budgeting. A table summarizing the types of reports, time for submission, and number of copies is set forth in Appendix A to this part.

Section 602.18 encourages participants to disseminate project results promptly and will allow DOE to waive technical reporting requirements if the information is published or accepted for publication in an appropriate journal.

Section 602.19 establishes requirements for project records and data. Because DOE is committed to the preservation and sharing of information with potential value for research or other purposes, projects are required to implement proper data and records management procedures. These procedures shall include development and maintenance of documentation for electronic data. The section also requires award recipients to comply with designated DOE records and data management needs, including providing information to the Comprehensive Epidemiologic Data Resource or to another repository, as DOE directs.

#### IV. Regulatory Review

Today's regulatory action has been determined not to be a "significant regulatory action" under Executive Order 12866, "Regulatory Planning and Review," (58 FR 51735, October 4, 1993). Accordingly, today's action was not subject to review under the Executive Order by the Office of Information and Regulatory Affairs.

#### V. Review Under the Regulatory Flexibility Act

This rule was reviewed under the Regulatory Flexibility Act of 1980

(Pub. L. 96-354, 95 Stat. 1164), which requires preparation of a regulatory flexibility analysis for any regulation that will have a significant economic impact on a substantial number of small entities; i.e., small businesses, small organizations, and small governmental jurisdictions. DOE concluded that this rule would only affect small entities as they apply for and receive awards and does not create additional economic impacts on such entities. Accordingly, DOE certifies that this rule will not have a significant economic impact on a substantial number of small entities and, therefore, no regulatory flexibility analysis has been prepared.

#### VI. Review Under the Paperwork Reduction Act

OMB has approved information collection requirements under this rule under control numbers 1910-0400 and 1910-1400.

#### VII. Review Under the National Environmental Policy Act

DOE has concluded that promulgation of this rule is categorically excluded under the DOE National Environmental Policy Act (NEPA) regulations (10 CFR part 1021, appendix A to subpart D) from preparation of either an Environmental Assessment or an Environmental Impact Statement under the NEPA of 1969 (42 U.S.C. 4321, et. seq. [1976]) as a rulemaking establishing application and review procedures for grants and cooperative agreements.

#### VIII. Intergovernmental Review

This program is generally not subject to the intergovernmental review requirements of Executive Order 12372, as implemented by 10 CFR part 1005. However, certain applications for financial assistance awards may require this review. Such applications, including those from governmental or nongovernmental entities that involve research, development, or demonstration activities, are subject to the provisions of the Executive Order and 10 CFR part 1005 when such activities: (1) have a unique geographic focus and are directly relevant to the governmental responsibilities of a State or local government within the geographic area; (2) necessitate preparation of an Environmental Impact Statement under NEPA; or (3) are to be initiated at a particular site or location and require unusual measures to limit the possibility of adverse exposure or hazard to the general public. Entities planning to submit such applications should contact the Office of Epidemiology and Health Surveillance (EH-42), U.S. Department of Energy, Washington, DC 20585 for further information.

## IX. Review Under Executive Order 12612

Executive Order 12612 requires review of regulations or rules for any substantial direct effects on States, on the relationship between National Government and the States, or on the distribution of power and responsibilities among various levels of Government. This rule amends, by addition of a new part, existing regulations for a financial assistance program to stimulate research and development. There will not be any substantial direct effects on States.

## X. Review Under Executive Order 12778

Section 2 of Executive Order 12778 instructs each agency to adhere to certain requirements in promulgating new regulations and reviewing existing regulations. These requirements, set forth in sections 2(a) and (b)(2), include eliminating drafting errors and needless ambiguity, drafting the regulations to minimize litigation, providing clear and certain legal standards for affected conduct, and promoting simplification and burden reduction. Agencies are also instructed to make every reasonable effort to ensure that the regulation: specifies clearly any preemptive effect, effect on existing Federal law or regulation, and retroactive effect; describes any administrative proceedings to be available prior to judicial review and any provisions for the exhaustion of such administrative proceedings; and defines key terms. DOE certifies that today's proposal meets the requirements of sections 2(a) and (b) of Executive Order 12778.

## XI. Catalog of Federal Domestic Assistance

The Catalog of Federal Domestic Assistance number for Epidemiology and Other Health Studies Financial Assistance Program is 81.108.

### List of Subjects in 10 CFR Part 602

Energy, Grant programs--health, Health, Medical research, Occupational safety and health, Reporting and recordkeeping requirements, Research.

For the reasons set forth in the preamble, chapter II of title 10 CFR is [[Page 5841]] amended by adding a new part 602, as set forth below.

Issued in Washington, DC, on January 18, 1995.  
Tara O'Toole,  
Assistant Secretary Environment, Safety and Health.



Chapter II of title 10 CFR is amended by adding part 602 to read as follows:

**PART 602--EPIDEMIOLOGY AND OTHER HEALTH STUDIES FINANCIAL ASSISTANCE PROGRAM**

Sec.

602.1 Purpose and scope.

602.2 Applicability.

602.3 Definitions.

602.4 Deviations.

602.5 Epidemiology and Other Health Studies Financial Assistance Program.

602.6 Eligibility.

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602.8 Application requirements.

602.9 Application evaluation and selection.

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602.11 Funding.

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602.13 Limitation of DOE liability.

602.14 Fee.

602.15 Indirect cost limitations.

602.16 National security.

602.17 Continuation funding and reporting requirements.

602.18 Dissemination of results.

602.19 Records and data.

**Appendix A to Part 602--Schedule of Renewal Applications and Reports**

Authority: 42 U.S.C. 2051; 42 U.S.C. 5817; 42 U.S.C. 5901-5920; 42 U.S.C. 7254 and 7256; 31 U.S.C. 6301-6308.

Sec. 602.1 Purpose and scope.

This part sets forth the policies and procedures applicable to the award and administration of grants and cooperative agreements by DOE (through the Office of Environment, Safety and Health or any office to which its functions are subsequently redelegated) for health related research, education/training, conferences, communication, and related activities.

Sec. 602.2 Applicability.

(a) This part applies to all grants and cooperative agreements awarded after the effective date of this rule.

(b) Except as otherwise provided by this part, the award and administration of grants and cooperative agreements shall be governed by 10 CFR part 600 (DOE Financial Assistance Rules).

### Sec. 602.3 Definitions.

In addition to the definitions provided in 10 CFR part 600, the following definitions are provided for purposes of this part:

Conference and communication activities means scientific or technical conferences, symposia, workshops, seminars, public meetings, publications, video or slide shows, and other presentations for the purpose of communicating or exchanging information or views pertinent to DOE.

DOE means the United States Department of Energy.

Education/Training means support for education or related activities for an individual or organization that will enhance educational levels and skills, in particular, scientific or technical areas of interest to DOE.

Epidemiology and Other Health Studies means research pertaining to potential health effects resulting from DOE or predecessor agency operations or from any aspect of energy production, transmission, or use (including electromagnetic fields) in the United States and abroad. Related systems or activities to enhance these areas, as well as other program areas that may be described by notice published in the Federal Register, are also included.

Principal investigator means the scientist or other individual designated by the recipient to direct the project.

Research means basic and applied research and that part of development not related to the development of specific systems or products. The primary aim of research is scientific study and experimentation directed toward advancing the state of the art or increasing knowledge or understanding rather than focusing on a specific system or product.

### Sec. 602.4 Deviations.

(a) Single-case deviations from this part may be authorized in writing by the Assistant Secretary for Environment, Safety and Health, the Head of the Contracting Activity, or their designees, upon the written request of DOE staff, an applicant for award, or a recipient. A request from an applicant or a recipient must be submitted to or

through the cognizant contracting officer.

(b) Whenever a proposed deviation from this part would be a deviation from 10 CFR part 600, the deviation must also be authorized in accordance with the procedures prescribed in that part.

#### Sec. 602.5 Epidemiology and Other Health Studies Financial Assistance Program.

(a) DOE may issue under this part awards for research, education/training, conferences, communication, and related activities in the Office of Environment, Safety and Health program areas set forth in paragraph (b) of this section.

(b) The program areas are:

- (1) Health experience of DOE and DOE contractor workers;
- (2) Health experience of populations living near DOE facilities;
- (3) Workers exposed to toxic substances, such as beryllium;
- (4) Use of biomarkers to recognize exposure to toxic substances;
- (5) Epidemiology and other health studies relating to energy production, transmission, and use (including electromagnetic fields) in the United States and abroad;
- (6) Compilation, documentation, management, use, and analysis of data for the DOE Comprehensive Epidemiologic Data Resource; and
- (7) Other systems or activities enhancing these areas, as well as other program areas as may be described by notice published in the Federal Register.

#### Sec. 602.6 Eligibility.

Any individual or entity other than a Federal agency is eligible for a grant or cooperative agreement. An unaffiliated individual is also eligible for a grant or cooperative agreement.

#### Sec. 602.7 Solicitation.

(a) The Catalog of Federal Domestic Assistance number for 10 CFR part 602 is 81.108 and its solicitation control number is EOHSFAP 10 CFR part 602.

(b) An application for a new or renewal award under this solicitation may be submitted at any time to DOE at the address specified in paragraph (c) of this section. New or renewal applications shall receive consideration for funding generally within 6 months but, in any event, no later than 12 months from the date of receipt by DOE.

(c) Except as otherwise provided in a notice of availability, applicants may obtain application forms, described in 602.8(b) of this part, and additional information from the Office of Epidemiology and Health Surveillance (EH-42), U.S. Department of Energy, Washington, DC 20585, (301) 903-5926, and shall submit applications to the same address.

(d) DOE will publish program notices in the Federal Register regarding the availability of epidemiology and other health studies financial assistance. DOE may also use other means of communication, as appropriate, such as the publication of notices of availability in trade and professional journals and news media.

(1) Each notice of availability shall cite this part and shall include:

(i) The Catalog of Federal Domestic Assistance number and solicitation control number of the program;

(ii) The amount of money available or estimated to be available for award;

(iii) The name of the responsible DOE program official to contact for additional [[Page 5842]] information and an address where application forms may be obtained;

(iv) The address for submission of applications; and

(v) Any evaluation criteria in addition to those set forth in Sec. 602.9 of this part.

(2) The notice of availability may also include any other relevant information helpful to applicants such as:

(i) Program objectives;

(ii) A project agenda or potential area of project initiatives;

(iii) Problem areas requiring additional effort; and

(iv) Any other information that identifies areas in which grants or cooperative agreements may be made.

(e) DOE is under no obligation to pay for any costs associated with the preparation or submission of applications.

(f) DOE reserves the right to fund, in whole or in part, any, all, or none of the applications submitted.

(g) To be considered for a renewal award under this part, an incumbent recipient shall submit a continuation or renewal application, as provided in Sec. 602.8 (c) and (h) of this part.

#### Sec. 602.8 Application requirements.

(a) An original and seven copies of the application for initial support must be submitted, except that State and local governments and Indian tribal governments shall not be required to submit more than the original and two copies of the application.

(b) Each new or renewal application in response to this part must include:

(1) An application face page, DOE Form 4650.2 (approved by OMB under OMB Control No. 1910-1400). However, the face page of an application submitted by a State or local government or an Indian tribal government shall be the face page of Standard Form 424 (approved by OMB under OMB Control Number 0348-0043).

(2) A detailed description of the proposed project, including its objectives, its relationship to DOE's program, its impact on the environment, if any, and the applicant's plan for carrying it out.

(3) Detailed information about the background and experience of the recipients of funds or, as appropriate, the principal investigator(s) (including references to publications), the facilities and experience of the applicant, and the cost-sharing arrangements, if any.

(4) A detailed budget for the entire proposed period of support with written justification sufficient to evaluate the itemized list of costs provided on the entire project. Applicants should note the following when preparing budgets:

(i) Numerical details on items of cost provided by State and local government and Indian tribal government applicants shall be on Standard Form 424A, "Budget Information for Non-Construction Programs" (approved under OMB Control No. 0348-0044). All other applicants shall use budget forms ERF 4620.1 (approved by OMB under Control No. 1910-1400).

(ii) DOE may, subsequent to receipt of an application, request additional budgetary information from an applicant when necessary for clarification or make informed pre-award determinations under 10 CFR part 600.

(5) Any pre-award assurances required pursuant to 10 CFR parts 600 and 602.

(c) Applications for a renewal award must be submitted with an original and seven copies, except that State and local governments and Indian tribal government applicants are required to submit only an original and two copies (Approved by OMB under OMB Control Numbers 0348-00050348-0009.)

(d) The application must be signed by an official who is authorized to act for the applicant organization and to commit the applicant to comply with the terms and conditions of the award, if one is issued, or if unaffiliated, by the individual applicant. (See Sec. 602.17(a)(1) for requirements on continuation awards.)

(e) DOE may return an application that does not include all information and documentation required by statute, this part, 10 CFR part 600, or the notice of availability, when the nature of the omission precludes review of the application.

(f) During the review of a complete application, DOE may request

the submission of additional information only if the information is essential to evaluate the application.

(g) In addition to including the information described in paragraphs (b), (c), and (d) of this section, an application for a renewal award must be submitted no later than 6 months before the expiration of the project period and must be on the same forms as required for initial applications. The renewal application must outline and justify a program and budget for the proposed project period, showing in detail the estimated cost of the proposed project, together with an indication of the amount of cost sharing, if any. The application shall also describe and explain the reasons for any change in the scope or objectives of the proposed project and shall compare and explain any difference between the estimates in the proposed budget and actual costs experienced as of the date of the application.

(h) DOE is not required to return an application to the applicant.

(i) Renewal applications must include a separate section that describes the results of work accomplished through the date of the renewal application and how such results relate to the activities proposed to be undertaken in the renewal period.

#### Sec. 602.9 Application evaluation and selection.

(a) Applications shall be evaluated for funding generally within 6 months, but in any event no later than 12 months, from the date of receipt by DOE. After DOE has held an application for 6 months, the applicant may, in response to DOE's request, be required to revalidate the terms of the original application.

(b) DOE shall perform an initial evaluation of all applications to ensure that the information required by this part is provided, that the proposed effort is technically sound and feasible, and that the effort is consistent with program funding priorities. For applications that pass the initial evaluation, DOE shall review and evaluate each application received based on the criteria set forth below and in accordance with the Office of Environment, Safety and Health Merit Review System developed, as required, under DOE Financial Assistance Regulations, 10 CFR part 600.

(c) DOE shall select evaluators on the basis of their professional qualifications and expertise. To ensure credible and inclusive peer review of applications, every effort will be made to select evaluators apart from DOE employees and contractors. Evaluators shall be required to comply with all applicable DOE rules or directives concerning the use of outside evaluators.

(d) DOE shall evaluate new and renewal applications based on the following criteria that are listed in descending order of importance:

- (1) The scientific and technical merit of the proposed research;
  - (2) The appropriateness of the proposed method or approach;
  - (3) Competency of research personnel and adequacy of proposed resources;
  - (4) Reasonableness and appropriateness of the proposed budget; and
  - (5) Other appropriate factors consistent with the purpose of this part established and set forth in a Notice of Availability or in a specific solicitation.
- (e) DOE shall also consider as part of the evaluation other available advice or information, as well as program policy [[Page 5843]] factors, such as ensuring an appropriate balance among the program areas listed in Sec. 602.5 of this part.
- (f) In addition to the evaluation criteria set forth in paragraphs (d) and (e) of this section, DOE shall consider the recipient's performance under the existing award during the evaluation of a renewal application.
- (g) Selection of applications for award will be based upon the findings of the technical evaluations (including peer reviews, as specified in the Office of Environment, Safety and Health Merit Review System), the importance and relevance of the proposal to the Office of Environment, Safety and Health's mission, and the availability of funds. Cost reasonableness and realism will also be considered.
- (h) After the selection of an application, DOE may, if necessary, enter into negotiations with an applicant. Such negotiations are not a commitment that DOE will make an award.

#### Sec. 602.10 Additional requirements.

- (a) A recipient performing research or related activities involving the use of human subjects must comply with DOE regulations in 10 CFR part 745, "Protection of Human Subjects," and any additional provisions that may be included in the special terms and conditions of an award.
- (b) A recipient performing research involving recombinant DNA molecules and/or organisms and viruses containing recombinant DNA molecules shall comply with the National Institutes of Health "Guidelines for Research Involving Recombinant DNA Molecules" (51 FR 16958, May 7, 1986), or such later revision of those guidelines, as may be published in the Federal Register. (The guidelines are available from the Office of Recombinant DNA Activities, National Institutes of Health, Building 31, Room BBB, Bethesda, MD 20892, or from the Office of Epidemiology and Health Surveillance, (EH-42), U.S. Department of Energy, Washington, DC 20585).
- (c) A recipient performing research on warm-blooded animals shall

comply with the Federal Laboratory Animal Welfare Act of 1966, as amended (7 USC 2131 et seq.), and the regulations promulgated thereunder by the Secretary of Agriculture at 9 CFR chapter I, subchapter A, pertaining to the care, handling, and treatment of warm-blooded animals held or used for research, teaching, or other activities supported by Federal awards. The recipient shall comply with the guidelines described in the Department of Health and Human Services Publication No. [NIH] 86-23, "Guide for the Care and Use of Laboratory Animals," or succeeding revised editions. (This guide is available from the Office for Protection from Research Risks, Office of the Director, National Institutes of Health, Building 31, Room 4B09, Bethesda, MD 20892, or from the Office of Epidemiology and Health Surveillance, (EH-42), U.S. Department of Energy, Washington, DC 20585).

#### Sec. 602.11 Funding.

(a) The project period during which DOE expects to provide support for an approved project under this part shall generally not exceed 3 years and may exceed 5 years only if DOE makes a renewal award or otherwise extends the award. The project period shall be specified on the Notice of Financial Assistance Grant (DOE Form 4600.1).

(b) Each budget period of an award under this part shall generally be 12 months and may be as much as 24 months, as DOE deems appropriate.

#### Sec. 602.12 Cost sharing.

Cost sharing is not required, nor will it be considered, as a criterion in the evaluation and selection process unless otherwise provided under Sec. 602.9(d)(5).

#### Sec. 602.13 Limitation of DOE liability.

Awards made under this part are subject to the requirement that the maximum DOE obligation to the recipient is the amount shown in the Notice of Financial Assistance Award as the amount of DOE funds obligated. DOE shall not be obligated to make any additional, supplemental, continuation, renewal, or other award for the same or any other purpose.



Sec. 602.14 Fee.

(a) Notwithstanding 10 CFR part 600, a fee may be paid, in appropriate circumstances, to a recipient that is a small business concern, as qualified under the criteria and size standards of 13 CFR part 121, in order to permit the concern to participate in the Epidemiology and Other Health Studies Financial Assistance Program. Whether or not it is appropriate to pay a fee shall be determined by the contracting officer, who shall, at a minimum, apply the following guidelines:

(1) Whether the acceptance of an award will displace other work that the small business is currently engaged in or committed to assume in the near future; or

(2) Whether the acceptance of an award will, in the absence of paying a fee, cause substantial financial distress to the business. In evaluating financial distress, the contracting officer shall balance current displacement against reasonable future benefit to the company. (If the award will result in the beneficial expansion of the existing business base of the company, then no fee would generally be appropriate.) Fees shall not be paid to other entities except as a deviation from 10 CFR part 600, nor shall fees be paid under awards in support of conferences.

(b) To request a fee, a small business concern shall submit with its application a written self-certification that it is a small business concern qualified under the criteria and size standards in 13 CFR part 121. In addition, the application must state the amount of fee requested for the entire project period and the basis for requesting the amount and must also state why payment of a fee by DOE would be appropriate.

(c) If the contracting officer determines that payment of a fee is appropriate under paragraph (a) of this section, the amount of fee shall be that determined to be reasonable by the contracting officer. The contracting officer shall, at a minimum, apply the following guidelines in determining the fee amount:

(1) The fee base shall include the estimated allowable cost of direct salaries and wages and allocable fringe benefits. This fee base shall exclude all other direct and indirect costs.

(2) The fee amount expressed as a percentage of the appropriate fee base, pursuant to paragraph (c)(1) of this section, shall not exceed the percentage rate of fee that would result if a Federal agency contracted for the same amount of salaries, wages, and allocable fringe benefits under a cost reimbursement contract.

(3) Fee amounts, determined pursuant to paragraphs (c)(1) and (c)(2) of this section, shall be appropriately reduced when:

(i) Advance payments are provided; and/or

(ii) Title to property acquired with DOE funds vests in the recipient (10 CFR part 600).

(d) Notwithstanding 10 CFR part 600, any fee awarded shall be a fixed fee and shall be payable on an annual basis in proportion to the work completed, as determined by the contracting officer, upon satisfactory submission and acceptance by DOE of the progress report. If the project period is shortened due to termination, or the project period is not fully funded, the fee shall be reduced by an appropriate amount.

#### Sec. 602.15 Indirect cost limitations.

Awards issued under this part for conferences and scientific/technical [[Page 5844]] meetings will not include payment for indirect costs.

#### Sec. 602.16 National security.

Activities under the Epidemiology and Other Health Studies Financial Assistance Program are not expected to involve classified information (i.e., Restricted Data, Formerly Restricted Data, National Security Information). However, if in the opinion of the recipient or DOE such involvement becomes expected prior to the closeout of the award, the recipient or DOE shall notify the other in writing immediately. If the recipient believes any information developed or acquired may be classified, the recipient shall not provide the potentially classified information to anyone, including DOE officials with whom the recipient normally communicates, except the Director of Declassification, and shall protect such information as if it were classified until notified by DOE that a determination has been made that it does not require such handling. Correspondence that includes the specific information in question shall be sent by registered mail to the U.S. Department of Energy, Attn: Director of Declassification, NN-50, Washington, DC 20585. If the information is determined to be classified, the recipient may wish to discontinue the project, in which case the recipient and DOE shall terminate the award by mutual agreement. If the award is to be terminated, all material deemed by DOE to be classified shall be forwarded to DOE in a manner specified by DOE for proper disposition. If the recipient and DOE wish to continue the award, even though classified information is involved, the recipient shall be requested to obtain both personnel and facility security clearances through the Office of Safeguards and Security for Headquarters awards or from the cognizant field office Division of

Safeguards and Security for awards obtained through DOE field organizations. Costs associated with handling and protecting any such classified information shall be negotiated at the time that the determination to proceed is made.

Sec. 602.17 Continuation funding and reporting requirements.

(a) A recipient shall periodically report to DOE on the project's progress in meeting the project objectives of the award. The following types of reports shall be used:

(1) Progress Reports. After issuance of an initial award, recipients must submit a satisfactory progress report to receive a continuation award for the remainder of the project period. The original and two copies of the required report must be submitted to the Office of Environment, Safety and Health program manager 90 days prior to the anticipated continuation funding date. The report should include results of work to date and emphasize findings and their significance to the field, and any real or anticipated problems. The report also should contain the following information: On the first page, provide the project title, principal investigator/project director name, period of time the report covers, name and address of recipient organization, DOE award number, the amount of unexpended funds, if any, that are anticipated to be left at the end of the current budget period. If the amount exceeds 10 percent of the funds available for the budget period, provide information as to why the excess funds are anticipated to be available and how they will be used in the next budget period. The report should state whether the aims have changed from the original application, and if they have, provide revised aims. A completed budget page must be submitted with the continuation progress report when a change to anticipated future costs will exceed 25 percent of the original recommended future budget.

(2) Notice of Energy Research and Development (R&D) Project. A Notice of Energy R&D Project, DOE Form 1430.22, which summarizes the purpose and scope of the project, must be submitted in accordance with the Distribution and Schedule of Documents set forth in Appendix A to this part, Schedule of Renewal Applications and Reports. Copies of the form may be obtained from a DOE contracting office.

(3) Special Reports. The recipient shall report the following events to DOE as soon after they occur as possible:

(i) Problems, delays, or adverse conditions that will materially affect the ability to attain project objectives or prevent the meeting of time schedules and goals. The report must describe remedial action that the recipient has taken, or plans to take, and any action DOE should take to alleviate the problems.

(ii) Favorable developments or events that enable meeting time schedules and goals sooner, or a lower cost than anticipated, or producing more beneficial results than originally projected.

(4) Final Report. A final report covering the entire project must be submitted by the recipient within 90 days after the project period ends or the award is terminated. Satisfactory completion of an award will be contingent upon the receipt of this report. The final report shall follow the same outline as progress reports. Recipients will provide, as part of the final report, a description of records and data compiled during the project, along with a plan for its preservation or disposition (see Sec. 602.19 of this part). All manuscripts prepared for publication should be appended to the final report.

(5) Financial Status Report (FSR) (OMB No. 0348-0039). The FSR is required within 90 days after completion of each budget period. For budget periods exceeding 12 months, an FSR is also required within 90 days after this first 12 months unless waived by the contracting officer.

(b) DOE may extend the deadline date for any report if the recipient submits a written request before the deadline, that adequately justifies an extension.

(c) A table summarizing the various types of reports, time for submission, and number of copies is set forth in appendix A to this part. The schedule of reports shall be as prescribed in this table, unless the award document specifies otherwise. These reports shall be submitted by the recipient to the awarding office.

(d) DOE, or its authorized representatives, may make site visits, at any reasonable time, to review the project. DOE may provide such technical assistance as may be requested.

(e) Recipients may place performance reporting requirements on a subrecipient consistent with the provisions of this section.

#### Sec. 602.18 Dissemination of results.

(a) Recipients are encouraged to disseminate research results promptly. DOE reserves the right to utilize, and have others utilize to the extent it deems appropriate, the reports resulting from research awards.

(b) DOE may waive the technical reporting requirement of progress reports set forth in Sec. 602.17, if the recipient submits to DOE a copy of its own report that is published or accepted for publication in a recognized scientific or technical journal and that satisfies the information requirements of the program.

(c) Recipients are urged to publish results through normal publication channels in accordance with the applicable provisions of 10

CFR part 600.

(d) The article shall include an acknowledgement that the project was supported, in whole or in part, by a DOE award, and specify the award number, but state that such support does not [[Page 5845]] constitute an endorsement by DOE of the views expressed in the article.

#### Sec. 602.19 Records and Data

(a) In some cases, DOE will require submission of certain project records or data to facilitate mission-related activities. Recipients, therefore, must take adequate steps to ensure proper management, control, and preservation of all project records and data.

(b) Awardees must ensure that all project data is adequately documented. Documentation shall:

- (1) Reference software used to compile, manage, and analyze data;
- (2) Define all technical characteristics necessary for reading or processing the records;
- (3) Define file and record content and codes;
- (4) Describe update cycles or conditions and rules for adding or deleting information; and
- (5) Detail instrument calibration effects, sampling and analysis, space and time coverage, quality control measures, data algorithms and reduction methods, and other activities relevant to data collection and assembly.

(c) Recipients agree to comply with designated DOE records and data management requirements, including providing electronic data in prescribed formats and retention of specified records and data for eventual transfer to the Comprehensive Epidemiologic Data Resource or to another repository, as directed by DOE. Recipients will provide, as part of the final report, a description of records and data compiled during the project along with a plan for its preservation or disposition.

(d) Recipients agree to make project records and data available as soon as possible when requested by DOE.

#### Appendix A to Part 602.--Schedule of Renewal Applications and Reports

Type	When due	Number of copies for awarding office
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1. Summary: 200 words on scope and purpose (Notice of Energy R&D Project).	Immediately after a grant is awarded and with each application for renewal.	3
2. Renewal period ends.....	6 months before the budget...	8
3. Progress Report period (or as part of a renewal application).	90 days prior to the next budget period.	3
4. Other progress reports, brief topical reports, etc. (Designated when significant results develop or when work has direct programmatic impact).	As deemed appropriate by DOE or the recipient.	3
5. Reprints, Conference.....	Same as 4. above.....	3
6. Final report of the project	Within 90 days after completion.	3
7. Financial Status Report (FSR).	Within 90 days after completion of the project period; for budget periods exceeding 12 months an FSR is also required within 90 days after the first 12-month period.	3

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Note: Report types 5 and 6 require with submission two copies of DOE Form 1332.16, University-Type Contractor and Grantee Recommendations for Disposition of Scientific and Technical Document.

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